

OPHTHALMIC DEVICES PANEL

One Hundred and Sixth Meeting

AGENDA

OCTOBER 3, 2003

8:30 A.M. – 4:00 P.M.

8:30	Call to Order	Jayne S. Weiss, M.D. - Chair
	Introductory Remarks	Sara M. Thornton - Executive Secretary
	Conflict of Interest Statement	
	Appointment to Temporary Voting Status	
	FDA Presentation	

8:45 - 9:15 **OPEN PUBLIC HEARING**

OPEN COMMITTEE SESSION

Jayne S. Weiss, M.D., Chair

9:15 - 9:30

DIVISION UPDATE

A. Ralph Rosenthal, M.D., Director

BRANCH UPDATES

James F. Saviola, O.D.

Chief, Vitreoretinal and Extraocular Devices Branch

Donna R. Lochner

Chief, Intraocular and Corneal Implants Branch

Everette T. Beers, Ph.D.

Chief, Diagnostic and Surgical Devices Branch

PMA P030016

9:30 - 10:30

SPONSOR PRESENTATION

10:30 - 11:00

Panel Questions for the Sponsor

11:00 - 11:20

FDA PRESENTATION

Donna Lochner – Introduction
Kesia Y. Alexander, Ph.D. – Team Leader
Malvina B. Eydelman, M.D. - Medical Officer
Gerry Gray, Ph.D. - Statistician

11:20 - 11:30

Panel Questions for FDA

11:30 - 11:35

Additional Comments from the Sponsor

11:35 - 12:35

LUNCH

12:35 – 4:00 p.m.

COMMITTEE DELIBERATIONS

Primary Panel Reviewers:

Dr. Marian S. Macsai-Kaplan
Dr. Joel Sugar
Dr. Michael R. Grimmett

PANEL DISCUSSION OF PMA P030016
to include FDA questions to the Panel

30-MINUTE OPEN PUBLIC HEARING SESSION

FDA – CLOSING COMMENTS (5 minutes)

SPONSOR – CLOSING COMMENTS (5 minutes)

Voting Options Read

PANEL RECOMMENDATION TAKEN BY VOTE

POLLING OF PANEL VOTES

COMMENTS FROM CONSUMER AND INDUSTRY REPRESENTATIVES

FINAL PANEL COMMENTS

4:00p.m.

OPEN MEETING ADJOURNED

NOTE: 15-MIN. BREAKS MAY BE GIVEN AT AN APPROPRIATE TIME DURING THE PROCEEDINGS